

International Health Law

JONATHAN TODRES AND PAMELA L. MARCOGLIESE*

In recent years, global health issues—including the continued spread of AIDS, outbreaks of severe acute respiratory syndrome (SARS) and avian influenza, as well as the threat of bioterrorism—have garnered increased attention by all countries. In 2004, this trend spurred efforts by the international community to further develop effective response systems to these and many other global health issues.

Perhaps as much as any other area covered by international law, health issues demand a coordinated effort by international, national, and local institutions.¹ Outbreaks of infectious disease that have the potential to spread rapidly across borders—such as SARS—have forced governments and health care professionals to rethink current response methods. Increasingly, countries are working to develop an international health law and policy framework that enables them to coordinate their responses and effectively address future public health crises.

International health, however, is not limited to public health emergencies. Over the past several years, it also has concentrated on a range of other issues, including developments in biomedical science (including stem cell research), pharmaceuticals and trade law issues, medical experimentation involving human subjects, and the intersection between health and human rights. The year 2004 witnessed a number of significant developments in international health law.

I. HIV and AIDS

In 2004, the spread of HIV/AIDS and efforts to control the disease continued to be among the most important international health issues. Numerous concerns arise in the

*Jonathan Todres is Chair of the International Health Law Committee of the ABA Section of International Law and is an Acting Assistant Professor at New York University School of Law. Pamela L. Marcogliese is a Vice Chair of the International Health Law Committee. This article covers events and developments that occurred from January 1, 2004 through December 31, 2004. As in prior years, space limitations for this article do not permit us to discuss many of the important developments in the field of international health law. The omission of an area of law or a particular development should not be construed as suggesting that such issue is not important.

1. See generally Allyn L. Taylor, *Shifting Norms in International Health Law*, 98 AM. SOC'Y INT'L L. PROC. 22 (2004) ("There is widespread recognition that national and international health are increasingly intertwined and inseparable.").

context of HIV and AIDS, including the adequacy of funding for HIV/AIDS programs, research and development, concerns over access to care (including the affordability and availability of antiretroviral therapies), discrimination against individuals living with HIV/AIDS, and the impact on children orphaned as a result of AIDS. Currently, approximately forty million people are living with HIV or AIDS.² In the past year, nearly five million people contracted the HIV virus, and over three million people died as a result of AIDS.³ Sub-Saharan Africa, home to over 60 percent of people living with HIV,⁴ continues to be the hardest hit region, although rates of infection are increasing in every region of the world, most dramatically in East Asia, Eastern Europe, and Central Asia.⁵ In addition, women and girls are increasingly affected by HIV/AIDS.⁶

Funding for HIV/AIDS programs received a boost in February 2004, as the United States announced its fifteen billion dollar, five-year global HIV/AIDS strategy.⁷ This initiative, known as the President's Emergency Plan for AIDS Relief (PEPFAR), has set goals of (1) treating two million HIV-positive people with antiretroviral therapy, (2) providing care for ten million people infected with and affected by HIV/AIDS, including children and orphans, and (3) preventing seven million new infections.⁸ While this new initiative is a welcome development in U.S. policy, there are a number of concerns, including the following: PEPFAR's bilateral structure provides little funding for the Global Fund to Fight AIDS, Tuberculosis, and Malaria, which currently is the accepted multilateral funding structure; PEPFAR does not sufficiently ensure the participation of local constituencies; funding for PEPFAR back-loads, rather than front-loads, resources; and PEPFAR may not adequately account for human rights issues that affect persons living with HIV/AIDS.⁹ Numerous other countries and private sector entities also contributed significantly to the funding of HIV/AIDS-related programs.

Throughout 2004, access to pharmaceuticals, in particular AIDS-related drugs, remained a primary focal point of debate. The World Health Organization (WHO), the Joint United Nations Program on HIV/AIDS (UNAIDS), and partner governments and agencies continued efforts to reach the announced targets of the "3 by 5" initiative.¹⁰ This initiative was launched in December 2003, to provide three million HIV-infected individuals, or half of all people in need, with treatment by the end of 2005.¹¹ By the end of 2004, 700,000 people living with AIDS in developing countries were receiving antiretroviral treatment as a result of these efforts, an increase of approximately 75 percent in the total number of treated

2. See Joint United Nations Programme on HIV/AIDS & World Health Organization, *AIDS Epidemic Update: December 2004*, available at http://www.unaids.org/wad2004/EPI_1204_pdf_en/EpiUpdate04_en.pdf.

3. *Id.* at 2.

4. *Id.* at 7.

5. *Id.* at 2.

6. *Id.* at 4. While women make up just under 50% of the current global HIV-positive population, 57% of HIV-positive individuals in Sub-Saharan Africa are women, and 76% of young people (15-24 year-olds) in that region living with HIV are female. This development raises questions concerning whether programs and services are adequately reaching women and girls.

7. Leonard S. Rubenstein & Eric A. Friedman, *Human Rights and the President's AIDS Initiative*, HUMAN RIGHTS MAG., Fall 2004, at 4, available at <http://www.abanet.org/irr/hr/fall04/initiative.htm>.

8. *Id.* at 4.

9. *Id.* at 4-5.

10. See World Health Organization, *700,000 People Living With AIDS in Developing Countries Now Receiving Treatment* (Jan. 26, 2005), available at <http://www.who.int/mediacentre/news/releases/2005/pr07/en/index.html>.

11. *Id.*

individuals from just one year ago.¹² Access to antiretroviral drugs remains an issue in the United States as well. In February 2004, the AIDS Healthcare Foundation, a California-based AIDS advocacy group, filed suit against Abbott Laboratories, claiming that a recent 400 percent increase in the price of an essential AIDS drug violated antitrust laws and constituted a restraint of trade.¹³ The case could have significant implications for drug pricing and access to pharmaceuticals.

Individuals with HIV/AIDS and their family members still confront discrimination in all sectors of society, ranging from discrimination in access to healthcare and other social services to workplace discrimination. In 2004, Non-governmental organizations and international agencies continued to pressure governments to better protect HIV/AIDS individuals from such discrimination and human rights abuses. As a result, a number of governments adopted or strengthened laws prohibiting discrimination against people with HIV/AIDS. For example, Indonesia adopted legislation mandating equal opportunity in the workplace for individuals living with HIV/AIDS and prohibiting employers from performing HIV tests as part of hiring requirements or routine medical exams.¹⁴ Similarly, Tanzania enacted new labor laws that included a prohibition on "direct or indirect discrimination in any employment policy" on the grounds of HIV/AIDS.¹⁵

Finally, in 2004, there was growing recognition of the impact of HIV/AIDS on the family members of those living with HIV/AIDS, especially children orphaned as a result of AIDS. Currently, an estimated fourteen million children are orphans because of AIDS.¹⁶ Research has found that children who are perceived to be HIV-positive, due to the death of a parent known to have AIDS, are stigmatized and isolated by their communities.¹⁷ They suffer discrimination in access to schools and health care facilities, and are at increased risk of exploitation through child labor and forced prostitution.¹⁸ Thus, even if these children are not HIV-positive, their health and well-being (and even their lives) are threatened, and additional efforts are needed to protect and provide for these children.

II. Infectious Disease Control

A. INTERNATIONAL HEALTH REGULATIONS

The primary international legal framework for infectious disease control is the International Health Regulations (IHR), originally promulgated in 1951.¹⁹ The IHR (1) provide

12. *Id.*

13. See *AIDS Healthcare Found. v. Abbott Labs.*, No. CV04-919 (RCx), (C.D. Cal., W. Div. filed Feb. 10, 2004); See also *Advocacy Group Files Suit on AIDS Drug Price Hike: AIDS Healthcare Found. v. Abbott Lab.*, 11 No. 11 ANDREWS HEALTH L. LITIG. REP. 14 (2004).

14. Decree of the Minister of Manpower and Transmigration of Republic of Indonesia on HIV/AIDS Prevention and Control in the Workplace, (Number: Kep. 68/MEN/2004) (Adopted Apr. 28, 2004), available at http://www.unaids.org/html/pub/topics/partnership-menus/indonesia_hiv-workplace_en.pdf.

15. Employment and Labour Relations Act (2004) (Tanz.), available at www.ilo.org/public/english/employment/gems/eo/law/tanzania/elra.htm.

16. Mark Katz, *HIV/AIDS: Twenty-two Years and Counting: Where are We?*, 25 WHITTIER L. REV. 233 (2003).

17. Ann Strode & Kitty Barrett Grant, *The Role of Stigma and Discrimination in Increasing the Vulnerability of Children and Youth Infected with and Affected by HIV/AIDS*, SAVE THE CHILDREN (UK), at 15 (Nov. 2001), available at <http://www.eldis.org/static/DOC15342.htm>.

18. *Id.*

19. World Health Organization, *Current International Health Regulations*, available at www.who.int/csr/ihr/current/en/print.html (last visited May 18, 2005). The IHRs apply to all 192 WHO Member States.

for notification to the WHO of cases of certain contagious diseases and coordination of any international response to covered outbreaks of such diseases; (2) establish health-related rules for international trade and travel; (3) outline procedures for governmental health agencies, such as public health controls related to goods at airports, ports, and other entry points; and (4) establish requirements for health and vaccination certificates for international travelers.²⁰ The IHR, last revised in 1969, were limited to three "notifiable diseases"—cholera, plague, and yellow fever.²¹ In light of recent outbreaks of SARS and avian influenza, the rapid spread of these diseases across borders, as well as potential outbreaks of small pox and other highly contagious diseases, governments and international health experts called for a broadening of the reach of the IHR. In November 2004, governments met to negotiate revisions to the IHR, based on a proposal by the WHO.²² The aim of the new IHR are to "prevent, protect against, control, and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade."²³ The new IHR, which also seek to establish more clearly the role for the WHO in leading and coordinating the response of various countries to outbreaks of infectious diseases, were adopted at the World Health Assembly meeting in May 2005.²⁴

B. REGIONAL EFFORTS

In addition to the revision of the IHR, there are also a number of ongoing regional efforts aimed at addressing infectious diseases. In April 2004, the European Union (EU) established an EU Centre for Disease Prevention and Control,²⁵ that is expected to become operational by May 2005.²⁶ The Centre was created in order to coordinate regional efforts dealing with communicable diseases. The EU regulation establishing the Centre outlines procedures for disease surveillance, scientific opinions, operation of an early warning and response system, scientific and technical assistance, identification of emerging health threats, and data collection and analysis.²⁷ Despite concerns about its limited funding, insufficient staffing and inadequate availability of facilities,²⁸ the Centre is "seen by the European Commission as having a key role to play in delivering the [EU]'s public health agenda in the face of infectious diseases like [SARS], bird flu, and HIV/AIDS."²⁹ Additionally, the Association of South Asian Nations (ASEAN) initiated a Southeast Asia regional program to

20. *Id.*

21. World Health Organization, *Review and Approval of Proposed Amendments to the International Health Regulations: Explanatory Notes, A/IHR/IGWG/4* (Oct. 7, 2004), at para. 3, available at http://www.who.int/gb/ghs/pdf/A_IHR_IGWG_4-en.pdf.

22. *Id.*

23. World Health Organization, *Revision of the International Health Regulations*, WHA58.3 (May 23, 2005), available at http://www.who.int/gb/ebwha/pdf_files/WHA58/WHA58_3-en.pdf.

24. *Id.*

25. European Parliament & Council of the European Union Regulation 851/2004 of 21 April 2004 Establishing a European Centre for Disease Prevention and Control, 2004 O.J. (L 142) 1-11.

26. Stephen Pincock, *Euro CDC Gathers Steam* (Sept. 29, 2004), available at <http://biomedcentral.com/news/20040929/01> [hereinafter *Euro CDC*].

27. *Id.*

28. Stephen Pincock, *ECDC Director Named* (Dec. 22, 2004), available at <http://www.biomedcentral.com/news/20041222/01> [hereinafter *ECDC Director*]; See also *Euro CDC*, *supra* note 26.

29. *ECDC Director*, *supra* note 28.

confront avian influenza with Thailand, Indonesia, Malaysia, Singapore, and the Philippines each responsible for coordinating specific measures to address the disease.³⁰

III. Pharmaceuticals

A. ACCESS TO AFFORDABLE MEDICINES

With the increasing cost of pharmaceuticals, access to affordable medicines is no longer an issue that solely affects developing countries. Rather, the governments of all nations must address their ability to provide affordable drugs to their citizens. Access to affordable medicines in the United States figured prominently as an issue for debate in the 2004 presidential election campaign.³¹ At the federal level, two reports ordered by the U.S. Congress were released by the Bush Administration in December 2004.³² In advising against the importation of pharmaceuticals from abroad, a view not unanimously endorsed, these reports take the position that, as a preliminary matter, the U.S. Food and Drug Administration (FDA) is unable to ensure the safety of pharmaceuticals purchased by individual consumers from other countries.³³ The reports further suggest that a federal system of bulk importation would facilitate oversight procedures, particularly if all drugs are imported from a single country (namely Canada).³⁴ Such a policy, however, would ultimately be disadvantageous to consumers because the decrease in profits for U.S. drug manufacturers would result in a corresponding reduction in spending on future research and development.³⁵

Despite the FDA's objection to the importation of pharmaceuticals, several states, including Illinois, Wisconsin, Missouri, and Kansas, are allowing their citizens to obtain prescription drugs from Canada at more affordable prices.³⁶ However, because the Canadian government is considering putting an end to this arrangement, these states are increasingly turning to countries in Europe, and possibly Australia and New Zealand, to provide their residents with affordable medicines.³⁷

On a more global scale, the trade-related aspects of Intellectual Property Rights (TRIPS) Agreement, created under the auspices of the World Trade Organization in 1995, has had a significant impact on access to medications.³⁸ For example, on December 31, 2004, the five-year transition period accorded to India, the world's largest producer of generic pharmaceuticals, came to an end.³⁹ As a result, the production of generic drugs in India must now comply fully with the TRIPS Agreement and, in particular, with the requirement that

30. *Asean Action Plan to Fight Bird Flu*, THE STRAITS TIMES (Sing.) (Dec. 22, 2004) (on file with author).

31. President George W. Bush and Senator John Kerry Second 2004 Presidential Debate Transcript, *available at* <http://64.233.161.104/search?q=cache:3DQPLWGpBf8J:www.4president.org/debates/2004Debate2.htm+2004+presidential+debates+pharmaceuticals&hl=en> (last visited July 23, 2005).

32. Rick Weiss, *Two Reports Fault Drug Importation*, WASH. POST, Dec. 22, 2004, at A25.

33. *Id.*

34. *Id.*

35. *Id.*

36. Associated Press, *Fearing End to Canada Drugs, States Now Look to Europe* (Jan. 14, 2005), *available at* <http://www.netdr.com/healthnews/canada-drugs.htm>.

37. *Id.*

38. Bonita de Boer, *TRIPS, AIDS and Generic Drugs*, *available at* <http://www.avert.org/generic.htm> (last modified Feb. 22, 2005).

39. *Id.*

India obtain a compulsory license to manufacture all drugs patented since 1995.⁴⁰ Not only is the compulsory licensing process demanding, but it can trigger adverse consequences because of the risk that large pharmaceutical companies will be reluctant to invest in countries that produce generic alternatives to their drugs.⁴¹ Furthermore, countries that are unable to produce their own affordable drugs must import them from other countries under specific circumstances and typically at costs that may exceed their available health care funding.⁴² In light of this international legal framework, India's compliance with the provisions of the TRIPS Agreement likely will hinder access to affordable pharmaceuticals from India in the most resource-constrained countries, further contributing to the public health crises facing countries most in need of affordable drugs.⁴³ Balancing intellectual property considerations with the need to ensure access to medicines will continue to be a major challenge in the foreseeable future.

B. RESEARCH AND DEVELOPMENT OF PHARMACEUTICALS

In response to the increasing cost of pharmaceuticals and the mounting difficulties of access to these drugs, alternative methods of financing research and development have emerged. For example, the Bill and Melinda Gates Foundation provides substantial funding for medical research.⁴⁴ This includes a \$168 million contribution for the research and development of a treatment for malaria.⁴⁵ This donation is an important example of a public/private initiative.⁴⁶ Similarly, in October 2004, as a result of a collaborative effort on the part of the Mozambican Ministry of Public Health and GlaxoSmithKline, researchers announced that, for the first time, a vaccine against malaria had proven effective in saving children from infection or death.⁴⁷ The vaccine was found to prevent infection in only 30 percent of cases and prevent life-threatening illness in 58 percent of cases.⁴⁸ Although these results are relatively low, considering that malaria kills over one million people a year, most of whom are children, this vaccine offers the hope of saving thousands of lives.

In September 2004, the University of California at Berkeley and the government of Samoa entered into an agreement that requires both parties to share equally in royalties derived from the sale of an anti-AIDS drug developed by using a Samoan native mamala tree.⁴⁹ The agreement also mandates that, in the event of any licensing of the drug to a pharmaceutical company, the drug must be made available in the developing world either

40. *Id.* Under TRIPS, generic versions of all drugs patented prior to 1995 may continue to be produced as before in India, but all drugs patented after this date require a compulsory license for production.

41. *Id.*

42. *Id.*

43. DFIC Health Systems Resource Centre, *Access to Medicines in Under-served Markets*, 12, 14 (Sept. 2004), available at <http://www.dfid.gov.uk/pubs/files/dfidsynthesispaper.pdf>.

44. Brian Carnell, *Bill Gates Donates \$168 Million for Malaria Research* (Nov. 29, 2003), available at <http://www.overpopulation.com/articles/2003/000080.html>.

45. *Id.*

46. *Id.*

47. Donald G. McNeil, *Malaria Vaccine Proves Effective*, N.Y. TIMES, October 15, 2004, at A1.

48. *Id.*

49. See Harvey Black, *Samoa to Benefit from AIDS Drug* (Oct. 1, 2004), available at <http://www.biomedcentral.com/news/20041001/02>.

on a no-cost basis or a nominal-cost basis.⁵⁰ The agreement is also important for the recognition that it provides to the essential intellectual contribution of Samoan healers.⁵¹

C. INFLUENZA VACCINES

In late 2004, the United States faced an influenza vaccine crisis when British regulators shut down the Chiron Corporation production facility in Liverpool, England, causing the United States to lose approximately half of its expected influenza vaccine supply.⁵² Most European countries, with the exception of Ireland, were only minimally affected by this shutdown, because, unlike the United States, they typically rely on multiple manufacturers to supply the needed vaccine.⁵³ This shortage illustrates the need for national governments to increase the number of sources from which they obtain their supply of influenza vaccine. In addition, because there is no incentive for companies to produce excess vaccine, given the frequent changes in the composition of the vaccine, this crisis also highlights the need for a concerted effort among vaccine manufacturers, licensing agencies, and national governments to ensure that a sufficient supply of influenza vaccine will always be available.⁵⁴ Experts believe that the crisis in the United States paled in comparison to the rationing and emergency measures that would be required in a pandemic.⁵⁵ While influenza annually causes the death of approximately 36,000 people in the United States and one million throughout the world, these figures represent only a fraction of the number of deaths expected in a pandemic, which typically occurs every twenty to thirty years.⁵⁶ In light of the increasing signs that avian influenza can be transmitted from person to person, many experts fear that a severe worldwide outbreak may be imminent.⁵⁷ In response to such a threat, on November 11, 2004, at an unprecedented emergency summit held in Geneva, Switzerland, the WHO called for international cooperation among all influenza vaccine producers and government health agencies to increase efforts aimed at eliminating the escalating threat of an influenza pandemic.⁵⁸

IV. Stem Cell Research

Many members of the medical and scientific community are hopeful that research conducted on embryonic and adult stem cells will yield treatments capable of curing serious diseases and reversing the effects of debilitating conditions. However, this potential for medical progress is fraught with legal and ethical considerations. Confronted with these

50. *Id.*

51. *Id.*

52. See Associated Press, *Few Flu Vaccine Shortages in Europe* (Oct. 21, 2004), available at <http://www.msnbc.msn.com/id/6300604/> [hereinafter *Few Flu Vaccine Shortages*]; see also David P. Fidler, *Influenza Vaccine Supply and International Law* (Oct. 2004), available at <http://www.asil.org/insights/2004/10/insight041020.htm>.

53. *Few Flu Vaccine Shortages*, *supra* note 52.

54. *Id.*

55. Associated Press, *WHO Calls Summit to Address Flu Pandemic* (Oct. 31, 2004), available at <http://abcnews.go.com/Health/wireStory?id=213667>.

56. *Id.*

57. *Id.*

58. Ned Stafford, *EU Underprepared for Flu* (Nov. 2, 2004), available at <http://www.biomedcentral.com/news/20041102/01>.

competing considerations, countries have been vigorously attempting to strike a balance between the promotion of scientific and medical research and the ethical issues related to the sanctity of human life. What follows is an overview of some of the most significant legal developments in this area that occurred during the past year.

A. INTERNATIONAL EFFORTS

In November 2004, after years of debate, the member states of the United Nations General Assembly legal committee considered two different proposals on the issue of human cloning.⁵⁹ The first, a proposal submitted by Costa Rica, contemplated a complete ban on all forms of cloning.⁶⁰ This proposal had the support of approximately sixty states, including the United States. In contrast, a resolution put forth by Belgium endorsed a ban on human reproductive cloning, while leaving to individual countries the discretion to address therapeutic cloning, through a complete ban, a moratorium, or other legislative approach.⁶¹ This measure was supported by the United Kingdom, China, and Finland, among other countries.⁶² On the last day of the meeting, Italy submitted a new proposal in an attempt to bridge the gap between the divided nations.⁶³ This compromise envisages a non-binding declaration aimed at encouraging member states to prohibit reproductive cloning and adopt legislation promoting "human dignity."⁶⁴ Based on the seemingly widespread support for this new proposal, a working group met in February 2005 to finalize the text of such a declaration.⁶⁵

B. UNITED STATES AND CANADA

At the federal level, the United States has largely taken a "market-oriented approach to stem cell research allowing virtually unfettered research in the private sector."⁶⁶ Throughout the 2004 presidential election campaign, President George W. Bush reiterated his opposition to federal funding of embryonic stem cell research that would result in the destruction of human embryos.⁶⁷ Instead, limited federal funds (approximately \$25 million per year) could be used for the continued research on existing stem cell lines.⁶⁸ Rather than implementing national stem cell legislation, the United States federal government preferred to leave the regulation of stem cell research to the individual states.

In November 2004, California voters passed Proposition 71, a \$3 billion measure, spread over ten years, creating an Institute for Regenerative Medicine focused on embryonic stem

59. Alison McCook, *UN Cloning Vote Likely this Week* (Nov. 17, 2004), available at <http://www.biomedcentral.com/news/20041117/02>.

60. *Id.*

61. *Id.*

62. *Id.*

63. Alison McCook, *UN Proposes Cloning Compromise* (Nov. 23, 2004), available at <http://www.biomedcentral.com/news/20041123/02>.

64. *Id.*

65. *Id.*

66. Kara L. Belew, *Stem Cell Division: Abortion Law and Its Influence on the Adoption of Radically Different Embryonic Stem Cell Legislation in the United States, the United Kingdom, and Germany*, 39 Tex. Int'l L.J. 479, 499 (2004).

67. Dan Vergano, *Stem-Cell Debate Another Division Between Bush, Kerry*, (Oct. 26, 2004), available at http://www.usatoday.com/news/politics/elections/nation/issues/2004-10-26-stem-cell-research_x.htm.

68. *Id.*

cell research.⁶⁹ Other states, in response to the success of Proposition 71, are developing funding measures in an attempt to halt an exodus of scientists to the West Coast. For instance, New York introduced a proposal which would grant \$1 billion in state funds to the creation and development of a stem cell research program and institute.⁷⁰ If the required governmental approvals are obtained, New Yorkers may vote on the proposal in an upcoming election.⁷¹ Similarly, in January 2005, legislators in Connecticut introduced a bill addressing the regulation and funding of stem cell research in the state.⁷² New Jersey also introduced a proposal in 2004 under which state funds would be used to create and support the New Jersey Institute for Stem Cell Research and to fund the New Jersey public/private stem cell fund.⁷³

On March 12, 2004, the Canadian Parliament passed An Act Respecting Assisted Human Reproduction and Related Research on March 12, 2004.⁷⁴ While the law allows embryonic stem cell research if certain conditions are met, it restricts the creation of embryos solely for research purposes.⁷⁵ The legislation also establishes the Assisted Human Reproduction Agency of Canada that is responsible for overseeing research using in vitro embryos.⁷⁶

C. EUROPE AND THE EUROPEAN UNION

The French National Assembly approved a bioethics law⁷⁷ that permits embryonic stem cell research provided that the principal aim of the research is the development of treatments for serious diseases. Scientists are permitted to use spare unfertilized eggs obtained from in vitro fertilization (IVF) clinics for this research, on the condition that the donors give their consent.⁷⁸ The law prohibits creation of embryos solely for research purposes. The legislation also provides for the establishment of a biomedicine agency in 2005 to oversee issues related to stem cell research.⁷⁹

The Spanish government approved a Royal Decree clarifying the existing regulations governing embryonic stem cell research.⁸⁰ Pursuant to the Royal Decree in 2004, scientists are permitted to conduct research on spare embryos from IVF clinics that have been frozen

69. Alison McCook, *An Eastern US Stem Cell Hub?* (Jan. 20, 2005), available at <http://www.biomedcentral.com/news/20050120/02/>; see also, Ivan Oransky, *California OKs Stem Cell Measure* (Nov. 3, 2004), available at <http://www.biomedcentral.com/news/20041103/02/>.

70. McCook, *supra* note 69.

71. *Id.*

72. *Id.*; see also, Steven Reinberg, *Connecticut Eyes Stem Cell Law*, THE SCIENTIST (Jan. 6, 2005), available at <http://www.biomedcentral.com/news/20050106/01/>.

73. McCook, *supra* note 69.

74. Assisted Human Reproduction Act, ch.2, 2004 S.C. (Can.), available at <http://laws.justice.gc.ca/en/A-13.4/3289.html>.

75. *Id.*

76. Doug Payne, *Canada Passes Cloning Law* (Mar. 16, 2004), available at <http://www.biomedcentral.com/news/20040316/03/>. See also Health Canada, *Assisted Human Reproduction Legislation Receives Approval of Senate* (Mar. 11, 2004), available at http://www.hc-sc.gc.ca/english/media/releases/2004/2004_10.htm.

77. Law No. 2004-800 of Aug. 6, 2004, J.O no. 182, Aug. 7, 2004, p. 14040 (Fr.), available at http://www.fivfrance.com/page_loi2004.html.

78. *Id.*

79. Jane Burgermeister, *France Green Lights Stem Cells* (Oct. 11, 2004), available at <http://www.biomedcentral.com/news/20041011/02/>.

80. Xavier Bosch, *Spain Eases Embryo Research*, THE SCIENTIST (Nov. 1, 2004), available at <http://www.biomedcentral.com/news/20041101/01/>.

for more than five years, if the donors have consented to the use of such embryos for research purposes.⁸¹ In connection with this Royal Decree, Spain's Health Minister stated that the government expects to approve a biomedical research law in 2005, that may include provisions related to therapeutic cloning and will likely allow embryonic stem cell research to be conducted on embryos that have been frozen for less than five years.⁸²

In 2004, the Swiss Parliament enacted legislation on embryonic stem cell research which permits the extraction of, and research on, human embryos up to seven days old provided that the donors have consented to the use of the spare embryo for research purposes.⁸³ The Swiss law also provides that, under certain conditions, embryonic stem cells may be imported from other countries for research purposes.⁸⁴ Although the United Kingdom has had legislation governing embryonic stem cell research in place since the Human Fertilisation and Embryology Act of 1990, on August 11, 2004, its Human Fertilisation and Embryology Authority granted a team of scientists from the University of Newcastle in Northern England permission to clone human embryos for exclusively scientific and medical purposes.⁸⁵ If successful, this would be the first case of cloning human embryos in Europe.⁸⁶

The EU is also developing a framework to address the issues surrounding embryonic stem cell research and human cloning. The same division among countries that manifested itself at the United Nations has similarly affected the European countries in their attempt to develop an acceptable framework for the EU. Nevertheless, some progress has been made.⁸⁷ The Treaty Establishing a Constitution for Europe (EU Constitution), expected to enter into force on November 1, 2006, contains language setting out certain parameters for the regulation of scientific and medical research.⁸⁸ Article II-63 of the EU Constitution provides the following principles: (1) the free and informed consent of the person concerned; (2) the prohibition of eugenic practices; (3) the prohibition of the commercialization of the human body and its parts; and (4) the prohibition of the reproductive cloning of human beings.⁸⁹

81. *Id.* See also Steven Ertelt, *Spain Advances Embryonic Stem Cell Research, Switzerland May Be Next* (Oct. 30, 2004), available at <http://66.195.16.55/bio536.html>.

82. Bosch, *supra* note 80.

83. Ned Stafford, *Swiss Support Stem Cells* (Nov. 29, 2004), available at <http://www.biomedcentral.com/news/20041129/02>.

84. *Id.*

85. Human Fertilization and Embryology Act, 1990, c. 37 (Eng.).

86. Jean-Yves Nadeau, *La Grande-Bretagne ouvre la voie au clonage d'embryons humains pour la recherche médicale* (Aug. 13, 2004), available at <http://www.lemonde.fr>.

87. See, e.g., Andrew Scott, *EU Clarifies Stem Cell Rules* (Nov. 5, 2003), available at <http://www.biomedcentral.com/news/20031105/06>; Andrew Scott, *Euro Parliament OKs Stem Cells* (Nov. 20, 2003), available at <http://www.biomedcentral.com/news/20031120/08>; Andrew Scott, *EU in Stem Cell Limbo* (Dec. 4, 2003), available at <http://www.biomedcentral.com/news/20031204/05>; Ned Stafford, *Potocnik Backs ES Cell Research* (Dec. 22, 2004), available at <http://www.biomedcentral.com/news/20041222/02>.

88. Treaty Establishing a Constitution for Europe, Dec. 16, 2004, O.J. (C 310) 1 (2004), available at <http://europa.eu.int/eur-lex/johtml.do?uri=OJ:C:2004:310:SOM:EN:HTML>.

89. *Id.* at art. II-63(2).

V. Right to Health

The newly adopted EU Constitution, although not yet in force, contains many provisions with implications for health care in the EU,⁹⁰ including the fundamental principle embodied in Article II-63 that all individuals have the right to “physical and mental integrity.”⁹¹ Article II-95 establishes that “[e]veryone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.”⁹² In addition to these specific health care provisions, the EU Constitution’s provisions regarding the environment also have implications for regional health efforts because of the environmental requirement to protect human health.⁹³ Finally, Article III-278 of the EU Constitution provides that “[a]ction by the [EU], which shall complement national policies, shall be directed towards improving public health, preventing human illness and diseases, and obviating sources of danger to physical and mental health.”⁹⁴ The EU Constitution specifies that such actions shall include “the fight against the major health scourges, by promoting research into their causes, their transmission and their prevention, as well as health information and education; [and] monitoring, early warning and combating serious cross-border threats to health.”⁹⁵

VI. WHO Framework Convention on Tobacco Control

In November 2004, the United Nations Treaty Section received the fortieth ratification for the WHO Framework Convention on Tobacco Control (WHO FCTC) and as a result the WHO FCTC entered into force on February 28, 2005.⁹⁶ The WHO FCTC, which was adopted unanimously by the WHO’s 192 member states in May 2003, is the first international legal instrument designed to reduce tobacco-related disease and deaths.⁹⁷ Currently, over 1.2 billion people in the world smoke⁹⁸ and approximately 4.9 million tobacco-related deaths occur each year.⁹⁹ This latter figure is higher than the annual number of

90. Health-related provisions in the EU Constitution include Articles II-61 (Human integrity), II-62 (Right to life), II-63 (Right to the integrity of the person), II-64 (Prohibition of torture and inhuman or degrading treatment or punishment), II-65 (Prohibition of slavery and forced labour), II-66 (Right to liberty and security), II-68 (Respect for private and family life), II-68 (Protection of personal data), II-69 (Right to marry and right to found a family), II-74 (Right to education), II-80 (Equality before the law), II-81 (Non-discrimination), II-82 (Cultural, religious and linguistic diversity), II-83 (Equality between men and women), II-84 (The rights of the child), II-85 (The rights of the elderly), II-86 (Integration of persons with disabilities), II-92 (Prohibition of child labour and protection of young people at work), II-93 (Family and professional life), II-94, (Social security and social assistance), II-95 (Health care), II-97 (Environmental protection), and II-98 (Consumer protection).

91. Treaty Establishing a Constitution for Europe, *supra* note 88, at art. II-63(1).

92. *Id.* at art. II-95.

93. *Id.* at art. III-233(1) (“Union policy on the environment shall contribute to . . . protecting human health”).

94. *Id.* at art. III-278(1).

95. *Id.*

96. World Health Organization, *WHO Tobacco Treaty Set to Become Law, Making Global Public Health History*, (Dec. 1, 2004) available at <http://www.who.int/mediacentre/news/releases/2004/pr89/en/>.

97. World Health Organization, *An International Treaty for Tobacco Control* (Aug. 12, 2003), available at <http://www.who.int/features/2003/08/en/>.

98. *Id.*

99. *Id.*

deaths related to AIDS, legal drugs, illegal drugs, road accidents, murder and suicide combined.¹⁰⁰ The impact of tobacco on the physical health of a population has significant implications for governments, businesses, and the environment.¹⁰¹ The resulting health, social, and economic costs provided the impetus for adoption of the WHO FCTC.

The WHO FCTC establishes a comprehensive framework for addressing the risks of exposure to and use of tobacco. States parties to the WHO FCTC must "adopt and implement effective legislative, executive, administrative and/or other measures and cooperate, as appropriate, with other [countries] in developing appropriate policies for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke."¹⁰² In particular, the WHO FCTC requires that states (1) implement restrictions on tobacco advertising, sponsorship, and promotion; (2) establish new packaging and labelling of tobacco products; (3) establish clean indoor air controls; (4) implement or revise legislation to eliminate tobacco smuggling; and (5) prohibit the sale of tobacco products to minors.¹⁰³ As of April 7, 2005, 168 countries had signed the WHO FCTC, including the United States, but only sixty-one countries had ratified or acceded to the WHO FCTC.¹⁰⁴ The United States has not yet ratified the WHO FCTC.¹⁰⁵

VII. Bioterrorism

Bioterrorism, now more than ever, is a significant threat to the health and safety of the world's population, and during 2004 cooperation at the international level continued to be a priority for many countries. In particular, at the G8 Summit held in June 2004, members reaffirmed their commitment to

concrete national and international steps to: expand or, where necessary, initiate new biosurveillance capabilities to detect bioterror attacks against humans, animals, and crops; improve [their] prevention and response capabilities; increase protection of the global food supply; and respond to, investigate, and mitigate the effects of alleged uses of biological weapons or suspicious outbreaks of disease. In this context, [they] seek concrete realization of [their] commitments at the fifth Review Conference of the [Biological and Toxin Weapons Convention].¹⁰⁶

G8 members recognized the importance of the 1972 Biological and Toxin Weapons Convention and the 1993 Chemical Weapons Convention as critical tools against the prolifer-

100. World Health Organization, *Building Blocks for Tobacco Control: A Handbook 6* (2004), available at <http://www.who.int/tobacco/resources/publications/general/en/HANDBOOK%20Lowres%20with%20cover.pdf>.

101. *Id.* at 11-12 (noting the costs to governments and employers of accommodating the sick, including increased expenditures on health care, the financial cost of absenteeism from work, and also environmental degradation as a result of the tobacco industry).

102. WHO Framework Convention on Tobacco Control, WHA Res. 56. 1, World Health Assembly, 56th Ass., 4th plea. mtg., Agenda Item 13, WHO Doc. A56.VR/4, art. 5(2)(b), available at http://www.who.int/gb/ebwha/pdf_files/WHA56/ea56r1.pdf.

103. WHO Framework Convention on Tobacco Control, WHA Res. 56. 1, World Health Assembly, 56th Ass., 4th plea. mtg., Agenda Item 13, WHO Doc. A56.VR/4, available at http://www.who.int/gb/ebwha/pdf_files/WHA56/ea56r1.pdf.

104. World Health Organization, *Updated Status of the WHO Framework Convention on Tobacco Control* (Feb. 27, 2005), available at <http://www.who.int/tobacco/framework/countrylist/en/>.

105. *Id.*

106. Press Release, Office of the White House Press Secretary, G8 Action Plan on Nonproliferation (June 9, 2004), available at <http://www.whitehouse.gov/news/releases/2004/06/20040609-28.html>.

eration of biological weapons, and they urged all nations who had not yet done so to promptly implement their provisions.¹⁰⁷

In 2004, the WHO also revised its 1970 publication *Health Aspects of Biological and Chemical Weapons*¹⁰⁸ and issued the *Public Health Response to Biological and Chemical Weapons: WHO Guidance*.¹⁰⁹ The new version provides information to assist nations in preparing for and responding to bioterrorism caused by the use of biological and chemical agents.¹¹⁰

VIII. Tsunami and Other International Disasters

As of late-January 2005, reports indicated that more than 212,000 people perished as a result of the tsunami that struck in the Indian Ocean on December 26, 2004.¹¹¹ While the international outpouring of generosity, including donations from governments, organizations and individuals, was rapid and widespread, this natural disaster has spurred the international community to consider again the need for an international framework to coordinate a response to global events and to redefine the role that international law should play in satisfying this need. A body of international law, including several treaties,¹¹² has already been developed to address man-made disasters of global proportions, and to provide guidance to help nations "prevent, prepare for, and respond to technological disasters with potential transboundary effects."¹¹³ Unlike man-made disasters, natural disasters cannot be prevented entirely through international cooperation. Rather, in such circumstances, the role of the international community is limited generally to the development of preparedness strategies and the coordination of relief.¹¹⁴

The International Disaster Response Law (IDRL) project, sponsored in 2000 by the International Federation of the Red Cross and Red Crescent Societies, concluded that the effectiveness and level of coordination of international responses to global disasters vary greatly from region to region.¹¹⁵ Such disparity was most recently exemplified by the response to the Indian Ocean tsunami when the IDRL project noted the difficulty of dealing with twelve different governments and with its own customs regulations.¹¹⁶ While the principle aim of the IDRL project is to identify how the response to international disasters could be improved through changes in national and international law,¹¹⁷ the World Con-

107. *Id.*

108. World Health Organization, *Health Aspects of Chemical and Biological Weapons: Report of a WHO Group of Consultants* (1970), available at <http://www.who.int/csr/delibepidemics/biochem1stenglish/en/>.

109. World Health Organization, *Public Health Response to Biological and Chemical Weapons: WHO Guidance* (2004), available at <http://www.who.int/csr/delibepidemics/biochemguide/en/index.html>.

110. *Id.*

111. *Tsunami deaths soar past 212,000* (Jan 19, 2005), available at <http://www.cnn.com/2005/WORLD/asiapcf/01/19/asia.tsunami/>.

112. For example, following the Chernobyl nuclear disaster, several treaties addressing nuclear energy facilities were concluded.

113. David P. Fidler, *The Indian Ocean Tsunami and International Law* (Jan. 2005), available at <http://www.asil.org/insights/2005/01/insight050118.htm>.

114. *Id.*

115. International Federation of Red Cross and Red Crescent Societies, *IDRL Legal Research: Research into Existing IDRL Treaties* (March 2003), available at <http://www.ifrc.org>.

116. Press Release, International Federation of Red Cross and Red Crescent Societies, *Tsunami Operation Offers Reminder of Need for Disaster Reduction Measures* (Jan. 12, 2005), available at <http://www.ifrc.org/docs/News/pr05/0605.asp>.

117. See Fidler, *supra* note 113.

ference on Disaster Reduction, sponsored by the United Nations, in Kobe, Japan in January 2005, considered whether the global impact of most natural disasters requires the further development of international law through multilateral conventions.¹¹⁸ Although the World Conference was scheduled prior to the occurrence of the tsunami, the tsunami was a prominent topic of discussion. The World Conference issued a Common Statement emphasizing the need for a coordinated international response to disasters and the importance of establishing tsunami early warning systems in the Indian Ocean region.¹¹⁹ It also adopted the Hyogo Declaration¹²⁰ and the Hyogo Framework for Action, 2005-2015,¹²¹ which recognize the importance of disaster reduction strategies, particularly through the use of international law, for achieving global sustainable development.

IX. Conclusion

All of the developments described in this article reflect the growing recognition of the important role of law and the legal community in international health. Multilateral and bilateral arrangements enable governments to coordinate responses to public health concerns. In addition, legislation provides incentives for healthcare organizations and professionals to promote and protect the public's health, and it helps alleviate disparities in access to and delivery of quality health care.¹²² The American Bar Association's House of Delegates adopted a recommendation in 2004 "urg[ing] its members and lawyers throughout the United States to improve their knowledge of public health law . . . [and] to become involved in assessing and improving the public health legal preparedness of the communities in which they live and work and ensuring that public health measures are protective of civil and constitutional rights."¹²³ Contributions from all sectors of society, including lawyers and health care professionals, are vital to the development of international health law and can help ensure that all countries develop appropriate responses to the health care needs of their population.

118. See World Conference on Disaster Reduction, *Brief history of the WCDR Process: Road to the WCDR*, available at <http://www.unisdr.org/wcdr/> (last visited May 19, 2005).

119. United Nations, World Conference on Disaster Reduction, *Common Statement of the Special Session on the Indian Ocean Disaster: Risk Reduction for a Safer Future* (Mar. 16, 2005) (Extract from the final report of the World Conference on Disaster Reduction (A/CONF.206/6)), available at <http://www.unisdr.org/wcdr/intergovt/official-doc/L-docs/special-session-indian-ocean.pdf>.

120. United Nations, World Conference on Disaster Reduction, *Hyogo Declaration* (Mar. 16, 2005) (Extract from the final report of the World Conference on Disaster Reduction (A/CONF.206/6)), available at <http://www.unisdr.org/wcdr/intergovt/official-doc/L-docs/Hyogo-declaration-english.pdf>.

121. United Nations, World Conference on Disaster Reduction, *Hyogo Framework of Action, 2005-2015* (Mar. 16, 2005) (Extract from the final report of the World Conference on Disaster Reduction (A/CONF.206/6)), available at <http://www.unisdr.org/wcdr/intergovt/official-doc/L-docs/Hyogo-framework-for-action-english.pdf>.

122. See George A. Mensah et al., *Law as a Tool for Preventing Chronic Diseases: Expanding the Spectrum of Effective Public Health Strategies*, 1 PREVENTING CHRONIC DISEASE 1 (Jan. 2004), available at http://www.cdc.gov/pcd/issues/2004/jan/pdf/03_0033.pdf.

123. American Bar Association, *Report: Public Health Law Awareness Among American Bar Association Members* (August 2004) (adopted by the American Bar Association House of Delegates), available at <http://www.abanet.org/leadership/2004/annual/dailyjournal/102.doc>.